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# The Frequency and Incremental Cost of Major Complications Among Medicare Beneficiaries Receiving Implantable Cardioverter-Defibrillators

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**OBJECTIVES** We aimed to quantify the frequency and nature of early complications after implantable cardioverter-defibrillator (ICD) implantation in general practice, and estimate the incremental costs of those complications to the health care system.

**BACKGROUND** Cardioverter-defibrillator implantation rates are rising quickly. Little has been published regarding the outcomes and costs of these procedures in unselected populations.

**METHODS** Using Medicare Provider Analysis and Review (MedPAR) files, we identified 30,984 admissions containing procedure codes for new ICD or cardiac resynchronization therapy defibrillator implantation in fiscal year 2003. The frequencies of eight complicating diagnoses during these admissions were determined. Length of stay (LOS) and total hospital costs, derived using whole-hospital cost to charge ratios, were calculated for each admission. The incremental effects of any and each complication on LOS and hospital cost were estimated in multivariable models, adjusting for demographic factors and comorbid conditions.

**RESULTS** The mean cost for all admissions was $42,184 (median $37,902) with mean LOS of 4.7 days (median 2.0 days). One or more complications were coded in 10.8% of admissions, most commonly "mechanical complication of the ICD" and hemorrhage/hematoma. The occurrence of any complication increased adjusted LOS by 3.4 days and costs by $7,251. Each of the individual complications was associated with highly significant increases in both LOS (1 to 10 days) and hospital cost ($5,000 to $20,000).

**CONCLUSIONS** In fiscal 2003, 10.8% of Medicare patients undergoing cardioverter-defibrillator implantation experienced one or more early complications, associated with significant increases in LOS and costs. Efforts to reduce these complications could have significant clinical and financial benefits. (J Am Coll Cardiol 2006;47:2493–7) © 2006 by the American College of Cardiology Foundation

Based on the findings of recent primary prevention trials (1–3), the utilization of implantable cardioverter-defibrillators (ICDs) in the U.S. is expected to increase at least two- to three-fold over the next several years (4). The financial implications of expanded cardioverter-defibrillator implantation have generated concern among large payers and some members of the clinical community, who feel that patient selection criteria could be better refined (4–8).

Little has been published concerning implant-related complications or costs based on large, unselected patient populations of ICD recipients. Analysis and reporting of ICD procedural complications will be of interest as non-electrophysiologists begin to implant more devices (9), and is an expressed goal of the newly created Medicare ICD registry (10).

The objectives of the present investigation were to estimate the cost of cardioverter-defibrillator implantation among Medicare beneficiaries in routine clinical practice, and to examine the frequency of and cost associated with major complications of cardioverter-defibrillator implantation.

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## METHODS

**Analytic cohort.** We obtained data for the current analysis from the Medicare Provider Analysis and Review (MedPAR) file for fiscal year 2003. The MedPAR files contain administrative data for all claims submitted to the Centers for Medicare and Medicaid Services (CMS) by U.S. short-stay hospitals for services provided to Medicare beneficiaries. For each hospitalization, the MedPAR files contain information on basic patient demographics (age, gender, race); admission and discharge dates; principal discharge diagnosis, coded according to the International Classification of Diseases-9th Revision-Clinical Modification (ICD-9-CM); up to eight secondary ICD-9-CM diagnosis codes; up to six ICD-9-CM procedural codes; and discharge status. Fiscal data for each admission include aggregrate and cost-center–specific hospital charges, total reimbursement, and the hospital's Medicare provider number. The validity of identifying comorbid conditions from such administrative data has been previously established (11).

The study population consisted of Medicare beneficiaries who underwent cardioverter-defibrillator implantation between October 1, 2002, and September 30, 2003, as identified by ICD-9-CM codes 37.94 (implantation or replacement of automatic cardioverter-defibrillator, total system) and 00.51 (implantation of a cardiac resynchroni-

**Abbreviations and Acronyms**

CMS = Centers for Medicare and Medicaid Services
CRT-D = cardiac resynchronization therapy-defibrillator
ICD = implantable cardioverter-defibrillator
ICD-9-CM = International Classification of Diseases-9th revision-Clinical Modification
LOS = length of stay
MEDPAR = Medicare Provider Analysis and Review

zation defibrillator, total system). These procedure codes are meant to specify total system implantation. Therefore, generator replacements, lead replacement/revision, and upgrade of prior devices generally should not have been included. Of the initial 53,936 cases identified using the above procedure codes, 22,952 patients who underwent one or more additional major cardiovascular procedures (cardiac catheterization, cardiac surgery, percutaneous coronary intervention, pacemaker or catheter ablation; Appendix Table 2) during the same admission were excluded from analysis in order to avoid confounding causes for in-hospital complications and costs of multiple procedures. The remaining 30,984 cases comprised the primary analytic cohort.

**Analytic methods.** Complications of interest for this analysis included: in-hospital death; implant-related infection; hematoma or hemorrhage; mechanical complication of the ICD (e.g., lead dislodgement); pneumothorax; cardiac perforation with pericardial effusion or tamponade; and acute renal failure with new-onset hemodialysis. These complications were selected based on review of pertinent clinical literature (1–3,12–16) and corresponding ICD-9-CM codes, in consultation with a hospital coder. The ICD-9-CM codes used to identify each of these complications are listed in the Appendix.

The outcome variables of interest, beyond the complications themselves, were length of stay (LOS) and total cost for the index hospitalizations. Length of stay was defined as the number of days from admission to discharge. Hospital cost was estimated by multiplying total charges submitted to CMS by the admitting hospital's overall cost-to-charge ratio, found in the 2003 or most recently settled Medicare Cost Report (17,18). This method of cost calculation thus does not include physician fees for services during the hospitalization.

**Statistical methods.** Data are presented as frequencies for discrete variables and mean values ± SD for continuous variables. The reporting of mean values is justified based on the large sample sizes, and because mean values best reflect expected expenditures from a payer perspective. Univariate between-group comparisons were performed using Fisher exact tests for binary variables, chi-square tests for categorical variables, and two-sample *t* tests for continuous variables. All reported p values are two-tailed. A p value $<0.05$ was considered to be statistically significant.

Multivariable linear regression models were constructed on the outcomes of total hospital cost and LOS, in order to estimate the incremental impact of individual complications on those outcomes, while adjusting for differences in baseline characteristics between subjects with and without complications. These models are adjusted for age, gender, race, and 32 comorbid conditions listed among the discharge diagnoses. The incremental resources associated with a particular complication were estimated as the regression coefficient for the dichotomous variable set to one if the patient experienced the complication and set to zero for all other patients. Although log-linear relationships were explored, we report only the results of the linear models, as the interpretation is more straightforward, and the results did not differ significantly between the two approaches. Separate models were also constructed with a term for any complication (versus none), adjusted for the same demographic and clinical variables, in order to estimate the incremental cost and LOS of having a complication of any kind. All analyses were performed using SAS version 8.2 statistical software (SAS Institute, Cary, North Carolina).

## RESULTS

In fiscal 2003, after excluding 21,952 patients who underwent additional invasive cardiovascular procedures during the same hospital admission, we identified 30,984 Medicare patients who underwent ICD (74.6%) or cardiac resynchronization therapy-defibrillator (CRT-D) (25.4%) implantations at 1,122 hospitals (median hospital implant volume = 15). The mean hospital cost for these admissions was \$42,184 ± \$23,199 (median \$37,902), and mean LOS was 4.7 ± 6.0 days (median 2.0 days). Mean unadjusted hospital costs were \$4,768 higher for admissions involving CRT-D implantation, compared with standard cardioverter-defibrillator implantation. This value was minimally changed after adjustment for patient characteristics, complications, and LOS.

**Table 1.** Frequency of Specific Complications During ICD Hospitalizations for the Entire Study Population, Stratified by Type of Implant

| Complication | ICD (n = 23,110) | CRT-D (n = 7,874) | p Value* |
|---|---|---|---|
| Any complication† | 11.0% | 10.5% | NS |
| Mechanical complication of ICD system | 4.8% | 3.8% | <0.001 |
| With lead or pocket revision | 1.2% | 1.8% | <0.001 |
| Hematoma/hemorrhage | 2.5% | 3.4% | <0.0001 |
| Infection associated with implant | 1.4% | 0.7% | <0.0001 |
| Pneumothorax | 1.0% | 1.2% | NS |
| Death | 0.9% | 1.1% | 0.07 |
| Other cardiac complications | 0.8% | 0.7% | NS |
| Pericardial effusion/tamponade | 0.3% | 0.3% | NS |
| Acute renal failure with new hemodialysis | 0.3% | 0.3% | NS |

*All p values are from Fisher exact tests; †complications are not mutually exclusive.
CRT-D = cardiac resynchronization therapy-defibrillator; ICD = implantable cardioverter-defibrillator.

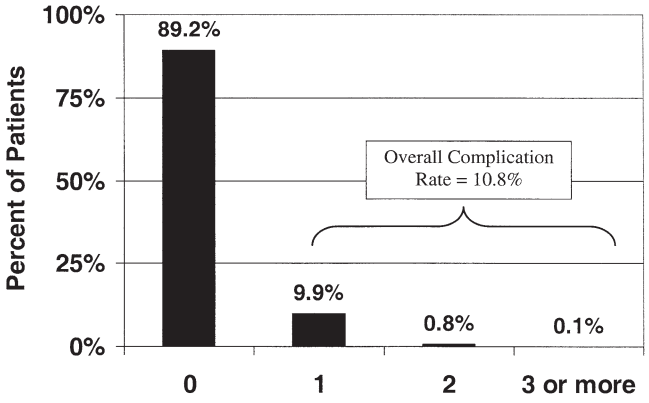


**Figure 1.** Frequency distribution of the number of complications for the entire study population.

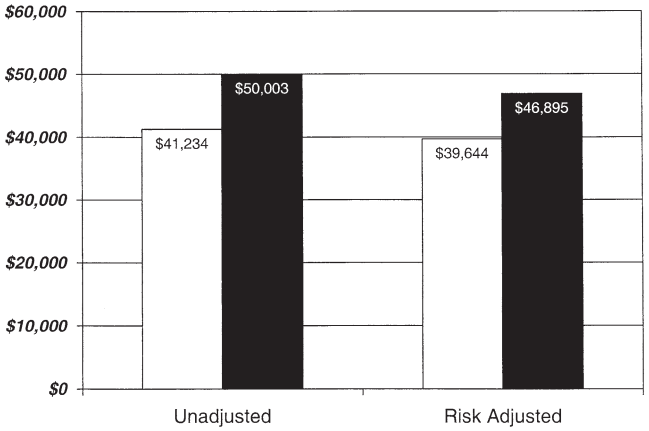


**Figure 2.** Observed and adjusted average hospital cost for patients with **(solid bars)** and without complications **(open bars)**.

Table 1 and Figure 1 summarize the frequency and nature of the complicating diagnoses documented in the MedPAR files. Overall, 10.8% of patients suffered one or more complications during the hospital stay in which their cardioverter-defibrillator was implanted. Most patients with complications had only one. The overall complication rate was similar whether an ICD or CRT-D device was implanted, although slight differences for a few individual complications were observed (Table 1).

Death occurred before hospital discharge in 0.9% of cases. Among patients who died, 33% had one or more additional complications as listed in Table 1 during the same hospitalization, most commonly "other cardiac complication" (8.4%), pneumothorax (6.3%), and mechanical complication of the ICD (5.6%).

The baseline characteristics of patients with and without complications during the same hospital admission as their ICD procedure are shown in Table 2. Patients who experienced complications, compared with those without, were slightly more often women and non-white, and more likely to have acute myocardial infarction, ventricular fibrillation, cardiac arrest, and chronic pulmonary or renal disease. Patients not experiencing an acute complication were more likely to have a diagnosis code for ventricular tachycardia and have a history of diabetes mellitus.

Patients with any complication, compared with those with none, generated $8,769 in increased hospital costs and 4.3 days in increased LOS in unadjusted analyses (Fig. 2). After adjustment for baseline patient characteristics, the difference in mean costs decreased to $7,251/patient and in LOS to 3.4 days.

Table 3 displays the adjusted incremental cost for each of the common individual complications observed, as well as the adjusted increase in hospital LOS. The listed complications each increased average hospital costs by between $5,000 (for pneumothorax) and $20,000 (for death), with

**Table 2.** Baseline Characteristics of ICD Recipients With and Without Acute Complications

| | Complication Group (n = 3,358) | No Complication Group (n = 27,626) | p Value |
|---|---|---|---|
| Demographics | | | |
| Age 65–74 yrs | 39.3% | 40.9% | 0.07* |
| 75–84 yrs | 39.9% | 39.5% | |
| >84 yrs | 5.8% | 5.8% | |
| Female gender | 23.3% | 21.0% | 0.002 |
| Non-Caucasian | 13.5% | 11.7% | 0.004 |
| Cardiac conditions | | | |
| CHF | 59.6% | 59.8% | NS |
| AMI (primary diagnosis) | 5.0% | 3.6% | <0.0001 |
| Cardiogenic shock | 1.5% | 0.3% | <0.0001 |
| Ventricular tachycardia | 57.0% | 65.9% | <0.0001 |
| Ventricular fibrillation | 8.6% | 6.1% | <0.0001 |
| Cardiac arrest | 3.2% | 1.3% | <0.0001 |
| Comorbid conditions | | | |
| Diabetes mellitus | 21.1% | 27.5% | <0.0001 |
| Chronic renal failure | 2.1% | 1.5% | 0.02 |
| COPD | 21.7% | 18.9% | <0.0001 |
| Cerebrovascular disease | 14.5% | 14.2% | NS |
| Device type | | | |
| CRT-D | 24.6% | 25.5% | NS |

*p value from chi-square test. All other p values in this table are from Fisher exact test.
AMI = acute myocardial infarction; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; CRT-D = cardiac resychronization therapy-defibrillator; ICD = implantable cardioverter-defibrillator.

**Table 3.** Adjusted Incremental Hospital Resource Utilization Associated With Treating Patients Experiencing the Complication of Interest

| Complication | Incremental Cost* | Incremental LOS (Days)* |
|---|---|---|
| Death | $20,547 | 8.3 |
| Infection associated with implant | $18,477 | 9.6 |
| Acute renal failure with new hemodialysis | $16,684 | 7.5 |
| Pericardial effusion/tamponade | $8,249 | 1.9 |
| Hematoma/hemorrhage | $6,995 | 3.1 |
| Other cardiac complications | $6,136 | 1.6 |
| Mechanical complication with lead or pocket revision† | $5,436 | 1.3 |
| Pneumothorax | $5,301 | 2.9 |

*All estimated incremental costs and length of stay (LOS) values are significantly different from zero ($p < 0.001$); †mechanical complication without code for lead/pocket revision associated with statistically non-significant change in-hospital costs.

associated increases in LOS from 1 to 10 days. The diagnostic code for mechanical complications of an ICD was associated with significantly increased cost and LOS only when a code for lead or pocket revision was also present. When a term for LOS was added to the model on costs, four of the eight complications (death, tamponade, mechanical complication with lead/pocket revision, and "other cardiac") were shown to increase costs independent of LOS; in other words, these complications increased both the intensity and duration of care.

Beyond the complications listed in the tables, an additional 1,492 patients (4.8%) were found to have diagnosis/procedure codes for acute renal failure or new-onset hemodialysis during the admissions in which their cardioverter-defibrillators were implanted. Because renal failure is not an expected complication of cardioverter-defibrillator implantation, we estimated incremental costs and LOS only for the small group coded for both acute renal failure and new hemodialysis.

## DISCUSSION

In this analysis of over 30,000 Medicare beneficiaries undergoing new cardioverter-defibrillator implantation in fiscal year 2003, we found that 10.8% experienced one or more complications before hospital discharge. On average, the occurrence of any complication increased adjusted hospital costs by ~$7,250, an increase of nearly 20% over an uncomplicated admission. If 100,000 cardioverter-defibrillators were implanted this year with similar results, the incremental cost of these complications would exceed $78 million.

Reported complication rates from cardioverter-defibrillator implantation may depend on the type of device implanted, and may also vary with definitions and the time frame of patient observation (19). Multicenter studies of early-generation transvenous ICDs reported surgical complication rates of 12% or higher (14,15). Common issues were lead dislodgement and wound or pocket problems. More recent ICD trials have reported lower acute complication rates, ranging from 1% to 8% (1–3,13), with the higher estimate including inappropriate shocks before hospital discharge (13). These recent trial data are concordant with survey data and single-center reports that estimate complication rates after pacemaker implantation of 4% to 7% (12,16).

Although direct comparisons are difficult, the overall frequency of complications in our study appears to be higher than that reported in recent clinical trials. Medicare patients who receive ICDs may, on average, be older and may have a higher prevalence of comorbid disease than typical clinical trial patients. A recent study also documented a relationship between low implant volumes and increased complication rates and found that the majority of implanting physicians in the U.S. had relatively low volumes of cases submitted to Medicare (20). Thus, higher complication rates may, to some extent, be expected in the Medicare population based on both patient and physician factors.

We did not find a difference in overall complication rates between ICD and CRT-D implants. In contrast, recent trials of CRT-D devices have reported higher (10% to 28%) frequencies of acute complications than those observed in recent ICD trials involving standard single and dual-chamber devices (21,22). This could be because only very skilled operators were implanting CRT devices in 2003, or because some CRT-D complications, such as lead dislodgement, may occur after the initial hospital discharge and may therefore have been underestimated by our methods.

The CMS has established a national ICD registry, in part to evaluate whether the costs and outcomes of cardioverter-defibrillator implantation differ in general practice compared with clinical trials (23). The present data support the rationale for this registry, and can serve as both benchmarks (e.g., for new implanting hospitals or physicians) and as targets for quality improvement. Previous studies indicate that several common complications of cardioverter-defibrillator implantation may be preventable (19,24–26). Our data suggest that dedicated quality improvement efforts could substantially enhance patient safety, and that, in light of their economic impact, successful initiatives to reduce procedural complications could pay for themselves.

Our data may also have implications for cost-effectiveness modeling. Trial-based analyses are able to directly incorporate observed complication costs in their calculations, but complication rates seen in the clinical trial setting are probably not representative of general practice. Model-based analyses, on the other hand, have either incorporated limited data on procedural complications (27) or have used old data for model inputs (28). In both scenarios, the true costs of procedural complications may have been underestimated.

Economic analyses of clinical trials also tend to focus on cardioverter-defibrillator implantation as an isolated procedure. This perspective would appear to grossly underestimate the true costs of providing care for the kind of patients in whom cardioverter-defibrillators are currently being implanted. Our data demonstrate that cardioverter-defibrillator implantation is very often performed as one of multiple invasive cardiac procedures during a single hospital admission. Even though we excluded patients with additional cardiac procedures from our analysis, the average hospital costs for our study cohort ($42,000, not including physician fees) were much higher than those used in contemporary ICD cost-effectiveness studies. The costs for hospitalizations in which cardioverter-defibrillators are implanted in addition to other cardiac procedures stand to be substantially higher.

Several important limitations of our study must be acknowledged. Our analyses rely on administrative data, which has well-recognized strengths and weaknesses. Both complications and comorbid illnesses could have been underreported. We made reasonable attempts to avoid confounding explanations for the complications that we defined, but cannot be certain that all of the complications we report were related to the implant procedures. Cardioverter-

defibrillator implants performed on an outpatient basis were not included. Potentially important clinical details were also unavailable; for example, the diagnostic code for "mechanical complications" (996.0), is non-specific, making clinical interpretation of its frequency difficult.

Our analysis was also limited to the hospitalizations during which cardioverter-defibrillators were implanted. Our estimates therefore represent a lower bound on the total frequency of cardioverter-defibrillator implant complications and their cost, which would also include physician fees for inpatient care, outpatient care, and re-hospitalizations. Some implant-related complications—in one pacemaker trial, as many as 30%—do not occur or are not recognized until after the initial hospitalization (20,29,30).

Finally, we estimated costs on the basis of hospital charges and whole-hospital cost to charge ratios. This method may be inaccurate for high-expense items like ICDs. Although hospital costs can be calculated more precisely using alternative methods, such methods are not practical to apply to a large national sample of hospitals.

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## APPENDIX

For supplementary tables 1 and 2, please see the online version of this article.